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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
ANDRES, JANET L

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1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,924	Applicant(s) CENTER ET AL.	
	Examiner Janet L Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 29-35* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☒ Claim(s) *29 and 31-33* is/are allowed.

6)☒ Claim(s) *21 and 35* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. Applicant's correction of the incorrect sequence in claim 31 results in the rejoining of Group IV with Group I; thus, claims 21, 29-33 and 35 are under examination to the extent that they read on the elected invention of antibodies to sequences comprising CLLS. Applicant has further traversed the restriction requirement on the ground(s) that the classification and fields of search of the groups are the same and further because Applicant states restriction may only be required if inventions are independent and distinct.

Applicant's arguments have been fully considered but have not been found to be persuasive. That the classification is the same does not indicate that the searches are identical. Each peptide is a separate entity that is searched separately. A search for sequences comprising CLLS will not uncover art relevant to sequences comprising WQALLS or QVVA. Furthermore, antibodies to each peptide are capable of supporting a separate U.S. patent.

Applicant further argues that inventions must be shown to be independent and distinct in order for a restriction requirement to be imposed. However, MPEP §802 states as follows:

802.01 Meaning of "Independent" and "Distinct"
35 U.S.C. 121 quoted in the preceding section states that the Commissioner may require restriction if two or more "independent and distinct" inventions are claimed in one application. In 37 CFR 1.141, the statement is made that two or more "independent and distinct inventions" may not be claimed in one application.
This raises the question of the subjects as between which the Commissioner may require restriction. This, in turn, depends on the construction of the expression "independent and distinct" inventions.
"Independent", of course, means not dependent. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the

codification of the patent laws indicate that 35 U.S.C. 121: "enacts as law existing practice with respect to division, at the same time introducing a number of changes." The report on the hearings does not mention as a change that is introduced, the subjects between which the Commissioner may properly require division.
The term "independent" as already pointed out, means not dependent. A large number of subjects between which, prior to the 1952 Act, division had been proper, are dependent subjects, such as, for example, combination and a subcombination thereof; as process and apparatus used in the practice of the process; as composition and the process in which the composition is used; as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word "independent" would clearly have been used alone. If the Commissioner has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions, e.g., the examples used for purpose of illustration above. Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term "distinct" with the term "independent", indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact,"distinct" inventions, even though dependent.

MPEP § 803 states,

There are two criteria for a proper requirement for restriction between patentably distinct inventions:
(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).
Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.

For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant.

Reasons in support of the restriction requirement were provided in the office action of paper no. 5. The requirement is still deemed proper and is therefore made FINAL. Applicant's comments with respect to the expense of applying for a patent and concerns with respect to

double patenting are noted. Claims 21 and 29-35 are pending in this application. Claims 21, 29-33, and 35 are under examination to the extent that they are drawn to the elected invention. Claim 34 is withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities: There are sequences in the brief description of the drawings on p. 15, lines 8, 9, 14, 16, and 17, p. 47, lines 6 and 32, and p. 58, line 26 that are not identified by reference to the identification number of an entered sequence. They must be referred to by a sequence identifier at every occurrence. In addition, lines 24-29 and line 32 of p. 16 and lines 1-8 and 21-22 of p. 53 refer to colors in figure 9, which is in black and white. There is also a blank space on p. 19, line 29. On p. 58, lines 18 and 20, one side of a set of parentheses appear to have been inadvertently added or omitted.

Appropriate correction is required.

The abstract of the disclosure is objected to because it is in two paragraphs. Correction is required. See MPEP § 608.01(b):

The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words. The abstract should not exceed 25 lines of text.

Claim Objections

3. Claim 30 is objected to because it contains sequences that are not referred to by reference to the identification number of an entered sequence.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 5171838 (Chiba, 1992), Moreland et al. (Arthritis and Rheumatism, Vol. 39, no. 9 (supplement), p. S244, 1996). Panayi et al. (Arthritis and Rheumatism, Vol. 39, no. 9 (supplement), p. S244, 1996), Choy et al. (Arthritis and Rheumatism, Vol. 39, no. 9 (supplement), p. S244, 1996), Connolly et al. (Arthritis and Rheumatism, Vol. 39, no. 9 (supplement), p. S245, 1996), Wending et al. (Arthritis and Rheumatism, Vol. 39, no. 9 (supplement), p. S245, 1996), and Reece et al. (Arthritis and Rheumatism, Vol. 39, no. 9 (supplement), p. S245, 1996).

These claims are drawn to antibodies against IL-16 inhibitory peptides comprising X-L-L-X. They thus encompass antibodies against any form of CD4 comprising CLLS and not bound to the cell surface, because any free form of CD4 that contained the IL-16 binding region would be interact with IL-16 and thus serve as a competitive inhibitor. Chiba teaches LEU3A, OKT4, EDU-2, T4/t19 Thy 5d7, F101-5, F101-65, 94bl, 91D6, MT310, MT321, MT151,VIT4, and OKT4D as monoclonal antibodies that react with CD4 (column 2, lines 5-10). Moreland et al., Panayi et al., Choy et al., Connolly et al., Wending et al., and Reece et al. similarly teach monoclonal antibodies against CD4. Each of these antibodies would bind a soluble CD4 molecule and thus meet the limitations of claims 21 and 35.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 21 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions comprising the 4162W94 antibody by virtue of the prior art, does not reasonably provide enablement for pharmaceutical compositions of antibodies against CD4 or regions thereof as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

This claim is drawn to a pharmaceutical composition. A "pharmaceutical composition" is one that is used therapeutically. Applicant has not, however, provided teachings that would allow one of skill in the art to predictably use the claimed composition to treat any disease or condition. While diseases affected by IL-16 are set forth on p. 32, no guidance is provided to indicate that antibodies against the D4 region of CD4 would affect such diseases. The specification provides no examples of any antibodies or their effects and no other guidance predictive of therapeutic effects. All that is shown is *in vitro* inhibition of cellular migration by peptides. The prior fails to provide compensatory teachings. While therapeutic results have been achieved with some antibodies, the art teaches that success is unpredictable. While Connolly et al., cited above, reports success with one antibody, Wendling et al., also cited above,

using another antibody, teach that "this placebo controlled study fails to demonstrate any significant improvement" in the treatment of rheumatoid arthritis. Thus, since the specification provides no working examples or other guidance to indicate that the anti-CD4 antibodies could be used to treat disease, and the prior art teaches that therapeutic results with such antibodies are unpredictable, the skilled artisan would require additional guidance to use pharmaceutical compositions of such antibodies with an expectation of success. Without such guidance, it would require undue experimentation for one of skill in the art to use the antibodies as broadly claimed as pharmaceutical compositions.

CLAIMS 21 AND 35 ARE REJECTED. CLAIM 30 IS OBJECTED TO. CLAIMS 29 AND 33-35 ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
February 21, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600